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To: In re the Application of	**FOR FILING IN THE** **U.S. PATENT AND TRADEMARK OFFICE**
Peter HAWKINS et al.	
Application No.: 09/816,225	Group Art Unit: 1600
Filed: March 26, 2001	Docket No.: 109068
For: PARAMAGNETIC PARTICLE DETECTION	

Examiner: P. Do   Facsimile: (703) 872-9306

From: Mario A. Costantino

Prepared By: ccs   Number of Pages Sent (Including cover sheet):   20

Comments:

Attached are copies of documents that were filed in the U.S. Patent and Trademark Office on December 15, 2003, for the above-identified application.

The following papers are attached:
a.   Transmittal of Copy of December 15, 2003 Appeal Brief and Appeal Brief Transmittal (2 pages)
b.   December 15, 2003 Appeal Brief (15 pages)
c.   December 15, 2003 Appeal Brief Transmittal (1 page)
d.   December 15, 2003 PTO-date-stamped receipt (1 page)

The U.S. Patent and Trademark Office is authorized to debit Deposit Account No. 15-0461 for any fees associated with this response.

Sent by: ms

PATENT APPLICATION

PATENT AND TRADEMARK OFFICE

BEFORE THE HONORABLE BOARD OF PATENT APPEALS AND INTERFERENCES

In re the Application of:

Peter HAWKINS et al. On Appeal from Group: 1600

Application No.: 09/816,225 Examiner: P. Do

Filed: March 26, 2001 Docket No.: 109068

For: PARAMAGNETIC PARTICLE DETECTION

TRANSMITTAL OF COPY OF DECEMBER 15, 2003 APPEAL BRIEF AND APPEAL BRIEF TRANSMITTAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The Examiner in charge of the above-identified application contacted Applicants' undersigned attorney on May 12, 2004, inquiring about the status of this application. In particular, the Examiner inquired as to whether an Appeal Brief had been filed. Applicants' undersigned attorney informed the Examiner that an Appeal Brief and Appeal Brief Transmittal were filed on December 15, 2003. However, the Patent Office does not have a copy of those documents.

Accordingly, Applicants submit the attached copies of the December 15, 2003 Appeal Brief and Appeal Brief Transmittal. Applicants also submit a copy of the PTO-date-stamped receipt, which evidences receipt of those documents by the Patent Office on December 15, 2003.

Action on the Appeal Brief is requested.

Respectfully submitted,

Mario A. Costantino
Registration No. 33,565

James A. Oliff
Registration No. 27,075

MAC:JAO/ccs

Attachments:
      December 15, 2003 Appeal Brief
      December 15, 2003 Appeal Brief Transmittal
      December 15, 2003 PTO-date-stamped receipt

Date: May 12, 2004

OLIFF & BERRIDGE, PLC
P.O. Box 19928
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The following papers have been filed:

Appeal Brief Transmittal, check no. 149273 ($330); Appeal Brief in triplicate

Name of Applicant:	Peter HAWKINS et al.
Serial No.:	09/816,225
Atty. File No.:	109068
Title (New Cases):	PARAMAGNETIC PARTICLE DETECTION
Sender's Initials:	JAO:PDM/ccs

139/26

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BEFORE THE HONORABLE BOARD OF PATENT APPEALS AND INTERFERENCES

In re the Application of:

Peter HAWKINS et al.	On Appeal from Group: 1600
Application No.: 09/816,225	Examiner: P. Do
Filed: March 26, 2001	Docket No.: 109068

For: PARAMAGNETIC PARTICLE DETECTION

APPEAL BRIEF TRANSMITTAL

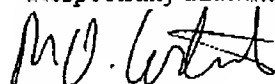Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Attached hereto are three (3) copies of our Brief on Appeal in the above-identified application.

Also attached hereto is our Check No. 149273 in the amount of Three Hundred Thirty Dollars ($330.00) in payment of the Brief fee under 37 C.F.R. 1.17(c). In the event of any underpayment or overpayment, please debit or credit our Deposit Account No. 15-0461 as needed in order to effect proper filing of this Brief.

For the convenience of the Finance Division, two additional copies of this transmittal letter are attached.

Respectfully submitted,

[signature] 33,565

James A. Oliff
Registration No. 27,075

Phillip D. Mancini
Registration No. 46,743

JAO:PDM/ccs

Date: December 15, 2003

OLIFF & BERRIDGE, PLC
P.O. Box 19928
Alexandria, Virginia 22320
Telephone: (703) 836-6400

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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE HONORABLE BOARD OF PATENT APPEALS AND INTERFERENCES

In re the Application of:

Peter HAWKINS et al.

Application No.:   09/816,225

Filed: March 26, 2001   Docket No.:   109068

For: PARAMAGNETIC PARTICLE DETECTION

BRIEF ON APPEAL

Appeal from Group 1600, AU1641

OLIFF & BERRIDGE, PLC
P.O. Box 19928
Alexandria, Virginia 22320
Telephone: (703) 836-6400
Attorneys for Appellants

TABLE OF CONTENTS

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I.   **REAL PARTY IN INTEREST**

The Assignee of this application, Randox Laboratories, LTD., by the Assignment recorded at Reel 011984, frame 0484, is the real party in interest.

II.   **RELATED APPEALS AND INTERFERENCES**

There are no related appeals or interferences.

III. **STATUS OF CLAIMS**

Claims 9-13 are pending. The attached Appendix includes a copy of each pending claim. Claims 1-8 and 14-26 were previously canceled. The Examiner's rejection of claims 9-13 set forth in the April 21, 2003, Office Action, is appealed.

IV.   **STATUS OF AMENDMENTS**

The claims were last amended in the July 17, 2003, Amendment After Final Rejection. No amendments have been filed after the July 17, 2003, Amendment After Final Rejection.

The Advisory Action indicates that for purpose of Appeal, the Amendment After Final Rejection will be entered.

V.   **SUMMARY OF INVENTION**

   A.   **Problems Addressed by the Invention**

The invention relates to paramagnetic particle detection and methods of determining the number of paramagnetic particles within a sample. In particular, the invention relates to a tuned circuit having a capacitor and a coil in which a difference in the resonant frequency of the tuned circuit is determined when the sample is and when the sample is not contained within the coil. This difference in the resonant frequency is used to determine the concentration of magnetic particles in the sample.

As described at page 1, starting at line 21, in a typical immunoassay, the paramagnetic particles (PMPs) are coated with proteins allowing them to be used as the solid phase material on which an immune reaction takes place. The immune reaction is detected and quantified

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using a label such as an enzyme, fluorescent or chemiluminescent molecule. The PMPs are not permanently magnetized but are attracted to the permanent magnets allowing simple washing procedures. Therefore, washing the coated PMPs does not require filtration or centrifugation. Following the washing steps, the immobilized label on the surface of the coated PMPs is detected using a suitable technique.

However, in existing detection techniques, the ferromagnetic particles are detected by a simple measuring coil which is placed in a Maxwell Bridge circuit to allow for measurement of the magnetic permeability of a sample. The magnetic permeability is then used as an indication of the number of particles within the sample. However, and as shown in Fig. 4 of Kriz et al., the use of a Maxwell Bridge circuit suffers from the consequence that precise results are difficult to achieve. Conventional methods such as that taught by Kriz et al. can only detect markers having a relative permeability of at least about 600 which means that the markers must be ferromagnetic and not paramagnetic. Furthermore, the capacitor and resistor in the bridge circuit of Kriz et al. have to be adjusted for each measurement.

B.   Description of the Claimed Invention

The present invention provides a method and apparatus for determining the number of magnetic particles within a sample. The present invention utilizes the fact that the presence of magnetic particles, such as paramagnetic particles, will lead to an inherent change in the permeability of a sample. Because the self inductance of a coil depends on the permeability of the material within the coil, placing a sample containing magnetic particles in a coil will result in a change in the inductance of the coil. The present invention utilizes this effect by obtaining an indication of the inductance of the coil by measuring the resonant frequency of an LC circuit including the coil. The resonant frequency will be different when the sample is placed within the coil compared to when the sample is removed from the coil. Accordingly, by

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measuring the change in the resonant frequency of the LC circuit, it is possible to determine the number of magnetic particles within the sample.

The resonant frequency of a practical LC circuit is very temperature dependent. Referring, for example, to the LC circuit shown in Fig. 1B, the circuit components vary with temperature and thus contribute to the drift in the resonant frequency with temperature. The coil in Fig. 1B was made from thin copper wire which increases in resistance with temperature. Additionally, the dimensions of the coil and the capacitance of the capacitor also change with temperature. The frequency of oscillation of an LC circuit, and hence the number of particles detected on a plastic strip containing the particles, is determined by using the LC circuit to control the frequency of oscillation of an oscillator circuit. Experimentation has shown that typically the resonant frequency decreases by only a few hertz when a plastic strip with particles on it is placed in a coil oscillating at about 250 kHz. The oscillator circuit therefore has to be very stable. However, oscillator circuits such as those shown in Fig. 2 were not found to be stable enough to permit these very small changes in frequency to be measured reliably. In the circuits shown in Fig. 2, the input impedance of transistor tr1 also affects the resonant frequency of the LC circuit and, as this is also temperature dependent, it adds to the instability of the oscillator. Thus, the most stable oscillator circuit was found to be one based on a phase-locked loop (PLL), an example of which is shown in Fig. 3.

The circuit shown in Fig. 3 comprises a voltage controlled oscillator VCO (VCO) 1 whose output is coupled to a frequency meter 2 and a phase detector 3. The output of the voltage controlled oscillator 1 also is coupled via a resistor 5 to a tuned LC circuit 4 which includes a coil L and a capacitor C. The phase detector 3 as well as being coupled to the output of the VCO1, is also coupled to the tuned circuit 4. The output of a phase detector 3 is transferred via a loop filter 6 to the VCO.

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When the tuned circuit 4 is in resonance, the potential differences across the inductor L and the capacitor C cancel each other out as they have exactly the same magnitude but are 180° out of phase with each other. The impedance of the LC circuit at resonance is entirely resistive and the current flowing in the circuit is in phase with the applied voltage. The potential difference across the resistor in series with the LC circuit is in phase with the applied voltage when the circuit is in resonance. The frequency at which this occurs is given by the equation $f = [2 \pi (LC)^{1/2}]^{-1}$ but with C replaced by $C + C_L$. This frequency is largely independent of R_L (which is probably one of the biggest contributors to the instability of the LC circuit).

Accordingly, the phase detector 3 is coupled to the output of the VCO1 so as to determine the phase of this driver signal, and to the tuned circuit 4 to determine the phase of the oscillation of the tuned circuit. The phase detector 3 then generates a DC signal representative of the difference in the phases of oscillation which is output to the loop filter 6. The loop filter filters the signal which is then returned to the voltage controlled oscillator 1.

The output frequency of the VCO is measured with a frequency meter. This circuit gives a considerably improved frequency stability, and frequency changes of less than 1 Hz in the resonance frequency of 200 to 300 kHz can be measured.

Fig. 4 illustrates performance of the PLL circuit shown in Fig. 3 using samples containing a relatively large number of PMPs in suspension. The samples were made with known concentrations of PMPs suspended in buffer solutions including 0, 1.03, 2.11, 4.19, 6.22 and 8.21 mg per ml. The samples were contained in sealed cylindrical plastic vials, 30 mm in diameter and 47 mm high. The vials contained 20 ml of suspension. The vials were shaken vigorously to ensure uniform mixing and placed in the coil attached to the phase locked loop circuit shown in Fig. 5 and the frequency of oscillation was measured. The sample vial was then removed and the increase in frequency noted. The experiment was repeated 10 times

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for all the vials and the difference in the two readings was plotted against the concentration of particles in the vials. The results clearly show that the decrease in resistance and frequency of the LC tuned circuit is directly related to the number of particles and suspension in the vile. This method was found to be very reliable, and it was possible to determine the concentration of particles in an unknown vial to a precision of better than 1%.

Response of the PLL circuit of Fig. 3 was then used to calculate the concentration of PMPs on standard plastic strips using a basic coil configuration. A test strip with a known number of PMPs on it was inserted into the coil L and the resonant frequency of the tuned circuit 4 was measured. The sample was then removed from the coil L and the resonant frequency again measured. The change in resonant frequency was noted. The experiment was repeated 10 times using the same test strip with concentrations varying from 3.33×10^6 to $1.6^8 \times 10^5$ particles applied to the plastic strip. The results are plotted on a log-log axis in Fig. 6 with a best straight line being determined using a linear regression. The points show the mean value of the readings for each sample and the arrow bars are the standard arrows of the mean. The PLL circuit has a good linear response to increasing the number of particles on a test strip as predicted by equation 6 ($F = F_0 [1 - \frac{1}{2} (K/L_0) \times N]$) with a sensitivity of about 0.16 Hz per 10^5 particles. Improved results can be achieved using smaller coils to reduce the dead space inside the coil and thus increase the sensitivity of the coil L in the PLL circuit of Fig. 3.

Thus, the disclosed method comprises immobilizing a layer of molecules to a substrate such as a test stick and providing a number of magnetic particles as labels. Then, a reaction is performed using the molecular layer so as to bind some of the magnetic particles to the substrate. Finally, the number of magnetic particles bound to the substrate can be determined by determining difference in resonant frequency of a tuned circuit when the substrate is exposed to a magnetic field generated by a coil in the circuit and when the substrate is not

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exposed to the magnetic field while the tuned circuit is connected to a phase locked loop. As

shown in Fig. 5, the phase locked loop comprises a driver which generates a driving signal for

driving the tuned circuit and a phase comparator for determining the phase difference between

the driving signal and an output signal obtained from the tuned circuit, the difference in

resonant frequency being determined by monitoring the performance of the phase locked loop.

VI.   ISSUES

A.   Whether the Office Action's Rejection of Claims 9-11
      and 13 under 35 U.S.C. §103(a) Over U.S.
      Patent 6,110,660 to Kriz et al. in view of U.S.
      Patent 5,978,694 to Rapoport is in Error

B.   Whether the Office Action's Rejection of Claim 12
      under 35 U.S.C. §103(a) as unpatentable over Kriz et
      al. in view of Rapoport and further in view of U.S.
      Patent 5,679,342 to Houghton et al. is in Error

VII.   GROUPING OF THE CLAIMS

Each claim of the patent application is separately patentable, and upon issuance of the

patent, will be entitled to a separate presumption of validity under 35 U.S.C. §282. For

convenience and handling of this appeal, the claims are grouped as follows:

Group I: Claims 9-11 and 13;

Group II: Claim 12

The groups do not fall together. However, because claim 12 includes all the features

of claim 9, the claim of group II is patentable for all the reasons set forth for the group I

claims.

VIII.   ARGUMENT

A.   Summary of the Relevant Law

In rejecting claims under 35 U.S.C. §103, it is incumbent on the Examiner to establish

a factual basis to support the legal conclusion of obviousness. In re Fine, 837 F.2d 1071,

1073, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). In so doing, the Examiner is expected to make

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the factual determinations set forth in Graham v. John Deere Co., 383 U.S. 1, 17-18, 148

USPQ 459, 467 (1966), and to provide a reason why one of ordinary skill in the pertinent art

would have been led to modify the prior art or to combine prior art references to arrive at the

claimed invention. Such reason must stem from some teaching, suggestion or implication in

the prior art as a whole or knowledge generally available to one having ordinary skill in the art.

Uniroyal Inc. v. F-Wiley Corp., 837 F.2d 1044, 1051, 5 USPQ2d 1434, 1438

(Fed. Cir. 1988), cert. denied, 488 U.S. 825 (1988); Ashland Oil, Inc. v. Delta Resins &

Refractories, Inc., 776 F.2d 281, 293, 227 USPQ 657, 664 (Fed. Cir. 1985), cert. denied, 475

U.S. 1017 (1986); ACS Hospital Systems, Inc. v. Montefiore Hospital, 732 F.2d 1572, 1577,

221 USPQ 929, 933 (Fed. Cir. 1984). These showings by the Examiner are an essential part

of complying with the burden of presenting a prima facie case of obviousness. In re Oetiker,

977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992).

The mere fact that the prior art may be modified in the manner suggested by the

Examiner does not make the modification obvious unless the prior art suggested the

desirability of the modification. In re Fritch, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1783-

84 (Fed. Cir. 1992). To establish prima facie obviousness of a claimed invention, all the claim

limitations must be suggested or taught by the prior art. In re Royka, 490 F.2d 981, 180

USPQ 580 (CCPA 1970). All words in a claim must be considered in judging the patentability

of that claim against the prior art. In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496

(CCPA 1970).

If the PTO fails to meet this burden, then the Applicant is entitled to a patent. In re

Glaug, 62 USPQ2d 1151 (Fed. Cir. 2002). In the present case, and as will be detailed below,

Appellants respectfully submit that the Examiner has failed to meet this burden, and that the

Office Action violates the substantive and procedural due process which the Patent Office is

supposed to accord Applicants via the Administrative Procedures Act. See in this regard,

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Dickinson v. Zurko, 527 U.S. 150, 50 USPQ2d 1930 (1999), and In re Gartside, 203 F.3d 1305, 1316, 53 USPQ2d 1769, 1776 (Fed. Cir. 2000).

B. THE 35 U.S.C. §103(a) REJECTIONS OF CLAIMS 9-13 LACKS FACTUAL SUPPORT

1. Claims 9-11 and 13

Claims 9-11 and 13 stand rejected under 35 U.S.C. §103(a) over U.S. Patent 6,110,660 to Kriz et al. in view of U.S. Patent 5,978,694 to Rapoport. This rejection is respectfully traversed.

With respect to independent claim 9, neither of the applied references discloses or suggests a method of performing a binding assay by determining the number of magnetic particles bound to a substrate comprising mobilizing a layer of molecules to a substrate, providing a number of paramagnetic particles as labels, performing a reaction using a molecular layer to bind at least some of the magnetic particles to the substrate and determining the number of magnetic particles bound to the substrate by determining the difference in resonant frequency of a tuned circuit when the substrate is exposed to a magnetic field generated by a coil and when the substrate is not exposed to the magnetic field generated by the coil, wherein the tuned circuit is connected to a phase locked loop comprising a driver which generates a driving signal for driving the tuned circuit and a phase comparator for determining the phase difference between the driving signal and an output signal obtained from the tuned circuit, the difference in resonant frequency being determined by monitoring the performance of the phase locked loop.

Claim 9 requires a phase locked loop. As noted above, Appellants' experimental results have determined that this allows more precise particle detection than other circuit configurations. As discussed in the specification of this application at page 15, lines 8-14, it has been found that using a phase locked loop leads to a very reliable response having a

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precision of better than 1 %. The Maxwell Bridge circuit of Kriz et al. as shown in Fig. 4 of Kriz et al., is incapable of achieving such precision. Thus, the paramagnetic particles detected by the claimed invention could not be detected by the device described by Kriz et al.

Neither Kriz et al. nor Rapoport discloses using a phase locked loop. Neither reference recognizes any advantage of using a phase locked loop. Thus, the references provide no motivation to obtain the claim 9 combination of steps.

Kriz et al. teaches a procedure for quantitative and qualitative determination of chemical substances, based on molecular recognition and measurement of magnetic permeability. In Kriz et al., the magnetic permeability of a material inside a coil influences the inductance of the coil. Thus, using the procedure of Kriz et al. it is possible to detect changes in magnetic permeability using inductance measurements. To measure the inductance, and thus indirectly, the relative magnetic permeability, the coil can be placed in the Maxwell bridge circuit. Kriz et al. teaches that the inductance can be measured in several different ways such as for example by placing the coil in an electrical measuring bridge such as a Maxwell bridge, by measurement of the resonance frequency for an LC-circuit of which the coil is a part, by applying a potential pulse and measuring the current response, by applying a current pulse or a non-constant current while monitoring the potential response by inductive coupling between two coils and by measurement of the coils impedance. See column 6 line 57 to column 7 line 6 of Kriz et al. However, Kriz et al. shows a preference for the Maxwell Bride approach over the resonance frequency measurements in col. 10, lines 41-43, which state that resonance frequency measurements were initially attempted, however the method gave poor results. The sensitivity observed was about 100 to 1000 times less than that using the Maxwell Bridge approach. Thus, Applicants submit that the claims of the instant application would not have been obvious in view of Kriz et al. because Kriz et al. teaches away from resonance frequency as a method of magnetic particle detection.

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Rapoport teaches a method and apparatus for detecting a magnetically responsive substance. The Office Action asserts that the first electrical conductor or coil of Rapoport is equivalent to the phase-locked loop of claim 9. However, Appellants respectfully submit that claim 9 recites a coil in addition to a phase-locked loop. As specified in claim 9, the difference in the resonant frequency of a tuned circuit is measured when the substrate is exposed to a magnetic field generated by a coil and when the substrate is not exposed to the magnetic field generated by the coil. The claim further specifies that the tuned circuit is connected to a phase-locked loop which comprises a driver which generates a driving signal for driving a tuned circuit and a phase comparator for determining the phase difference between the driving signal and an output signal obtained from the tuned circuit, the difference in resonant frequency being determined by monitoring the performance of the phase-locked loop. However, Rapoport teaches away from a phase locked loop by stating that depending on the performance characteristics of the conductor 12 being measured, the measuring device 19 can be a voltmeter, a potentiometer, and ammeter, or other known device. See col. 4, lines 64-67. These devices are not analogous to a phase locked loop.

The Examiner supports her position by asserting that Kriz et al. teaches an LC circuit containing a coil and Rapoport teaches a device which comprises a first electrical conductor which can be a coil. The Examiner also asserts that the device of Rapoport further comprises a means for applying a known electromagnetic signal to the first electrical conductor to provide a change in the signal which can be measured to indicate the presence of the substance of interest. The Examiner suggests that such means is equivalent to the driver of the claimed invention and is therefore equivalent to the phase locked loop because claim 9 recites that the phase locked loop comprises, among other things, a driver. Even if it can be assumed that the means of Rapoport is equivalent to the driver recited in claim 9, at least one other claimed component of the phase locked loop is not addressed by the rejection. Specifically, the second

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electrical conductor of Rapoport referred to by the Examiner is not analogous to a phase comparator.

Therefore, based on the deficiencies of the combination of references in teaching the claimed invention, Appellants respectfully submit that claim 9 and its dependent claims 10, 11 and 13 are patentable over the combination of applied references. The Examiner has failed to establish a *prima facie* case of obviousness against the claims.

2.   Claim 12

Claim 12 stands rejected under 35 U.S.C. §103(a) over Kriz et al. and Rapoport and further in view of U.S. Patent 5,679,342 to Houghton et al. This rejection is respectfully traversed.

Houghton et al. does not provide the deficiencies of Kriz et al. and Rapoport set forth above with respect to independent claim 9 and dependent claims 10, 11 and 13. Accordingly, claim 12 is patentable at least for the reasons set forth above with respect to claims 9-11 and 13.

Accordingly, this rejection should be withdrawn as well.

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Application No. 09/816,225

IX. CONCLUSION

For at least the reasons set forth above, it is respectfully submitted that claims 9-13 are

patentable over the applied references. Appellants request this honorable board to reverse the

rejections of the claims.

Respectfully submitted,

/nO. Ortiz 33,565

James A. Oliff
Registration No. 27,075

Phillip D. Mancini
Registration No. 46,743

JAO:PDM/ccs

Enclosure:
    Appendix

Date: December 15, 2003

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Alexandria, Virginia 22320
Telephone: (703) 836-6400

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